

REMARKS

Reconsideration is hereby requested, as is a three-month extension of time within which to respond to the Official Action. The Small Entity extension of time fee therefore in the amount \$460 is enclosed herewith.

Responsive to ¶s 1-4 of the Official Action, all objections and rejections of record under 35 U.S.C. 112 have been responded to through the re-drafting of Claims 1-4, 8 and 11 as new Claims 14-19. Original Claim 10 has not been replaced by any substitute claim. The antecedent basis of Claim 15 relative to the term "grid-like" appears at Page 21, ¶2, of the specification. Accordingly, all objections and rejections under §112 have been responded to.

With regard to the rejection under 35 U.S.C. 102(b) (¶5 of the Official Action), Applicants respectfully note that the reference to Branemark relates to a range of pore diameters, i.e., a "micro-pitted" surface which is in a range of 10 nanometers to 1,000 nanometers. Given that 1,000 nanometers equal 1 micron, the uppermost range of the magnitude of the micro-pits of Branemark is one-half of the low end of Applicants' range of dimension of parallel alternating ridges and grooves. As such, most of the range of 10 to 1,000 nanometers of Branemark constitutes a surface far too smooth to produce an orientation and direction of growth of colonies of cells in contact with an implant surface.

Further, Branemark does not teach a repetitive surface pattern of any type. Rather, he teaches the use of an entirely random surface pattern having no structure apart from that of a "pit," whatever that may actually mean. As such, neither the geometry nor the order of magnitude of the pits of Branemark are germane to the invention of the within Applicants.

With respect to the rejection of Claims 1-13 under 35 U.S.C. 102(e), as anticipated by Naiman et al (U.S.P.N. 5,607,607), Applicants include herewith a Declaration under 37 CFR 1.131, submitted by the same inventive entity with respect to the parent of the instant application, that is, Application Serial No. 09/500,038 (now U.S. Patent No. 6,419,491). This declaration sets forth that the instant invention well pre-dated the laser-related work of Naiman of U.S.P.N. 5,607,607 and its effective date of November 1, 1993 (one day prior to the priority date of this application), and that Naiman was a common member of both inventive entities. See ¶s 1-9 thereof. As may be appreciated from said Declaration, the invention of Naiman '607 occurred as a consequence of the instant invention, not *vice versa*.

With respect to the rejection of Claims 1-3, 5-7, 9 and 11, under 35 U.S.C. 103(a) over Lin in view of Mears, Applicants note that the teaching of Mears is one of a system having a pore size in a range of 25 to 400 microns. That is, the lowest end of the range of Mears constitutes the upper limit (25 microns) of the range of Applicants. In addition, as is the case in Branemark,

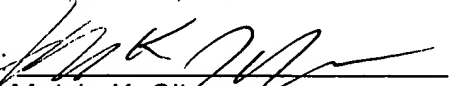
discussed above, the teaching, as to geometry of the microscopic surface patterns of Mears, is simply that of pores having no particular arrangement or pattern (see for example Figs. 3-6 of Mears). Thereby, neither the dimensionality of the pores of Mears, nor the geometry thereof bears any particular relationship to that claimed by Applicants.

Applicants also note that the reference to Lin relates to a dissolvable spacer when used in a calcium sulfate acid etch process on a plastic surface. Thereby, the acid etch mask and process of Lin is not applicable to high density materials, such as titanium, stainless steel, ceramics, Hensch glass, and combinations thereof employed as a base material in Applicants implant. The reference to Lin is also discussed by Applicants in the Background of the Invention (Page 7, ¶1 thereof) in the context of softer surfaces such as aluminum or zinc.

In view of the above, the Claims as amended overcome all objections and rejections of record and, as such, the early allowance thereof is solicited.

Respectfully submitted
JOHN L. RICCI, et al

BY:


Melvin K. Silverman
Reg. No. 26,234



MARKED-UP ORIGINAL CLAIMS OF
S.N. 09/784,284

THE CLAIMS

We claim:

14. [1] An orthopedic implant comprising an implant element for surgical insertion into a bone or bone-related tissue and of a patient, said implant element comprising a[n ordered microgeometric] micro-geometric, repetitive surface pattern in a form of a multiplicity of substantially parallel alternating ridges and grooves, each having an established width in a range of about 2 to about 25 microns, and an established depth in a range of about 2 to about 25 microns,

whereby said micro-geometric repetitive pattern defines a guide for [a preferential] promotion of [the] rate, orientation and direction of growth of colonies of cells of said bone which are in contact with said surface pattern.

15 [2] The implant as recited in Claim 14 [1], in which said implant element comprises a gridlike [n orthonormal] matrix of said pattern of alternating ridges and grooves.

16 [3] The implant as recited in Claim 14 [1], in which [said multiplicity comprises a first multiplicity of] said alternating ridges and grooves [includes an axis] are oriented [co-]parallel with a [major] longitudinal axis of said implant.

17 [4] The implant as recited in Claim 3 [comprising a second multiplicity of] in which said alternating ridges and grooves are oriented transversely, to said [major] longitudinal axis of said [first multiplicity] implant.

5. The implant as recited in Claim 14 [1] in which base materials of said implant are selected from the group consisting of the materials of titanium and alloys thereof, stainless steel, ceramics, biocompatible glass and combinations thereof.

6. The implant as recited in Claim 15 [2] in which said orthonormal matrix is oriented diagonally relative to a major axis of the implant.

7. The implant as recited in Claim 14 [1] in which said repetitive micro-geometric pattern of ridges and grooves comprises application to surfaces of said implant element in orientations which, relative to a longitudinal axis of said implant, are selected from the group consisting of vertical, horizontal, orthonormal diagonal, radial, circumferential, and concentric orientations.

18 [8] The implant as recited in Claim 5 in which a surface of said implant element comprises a surface [coating] selected from the group of surfaces consisting of hydroxyapatite, RBM roughening, titanium, plasma sprayed, calcium sulfate, biocompatible glass, collagen, growth factor compounds, and combination thereof.

9. The implant as recited in Claim 14 [1] in which said orthopedic implant is selected from the group consisting hip, knee, shoulder, elbow, ankle and finger implants.

[10. The implant as recited in Claim 9 in which said implants are selected from the group consisting of bone and soft tissue anchors.]

19. [11] The implant as recited in Claim 9 in which said repetitive micro-geometric pattern comprises a product of [the process selected from] the process group consisting of laser etching, acid etching, mechanical etching, and photolithography.

12. The implant as recited in claim 9 comprising different zones furnished with respectively different surface patterns.

13. The implant as recited in Claim 12 in which said different zones include respective hard and soft tissue contact zones.



New and amended Claims for Serial No. 09/784,284

5. The implant as recited in Claim 14 in which base materials of said implant are selected from the group consisting of the materials of titanium and alloys thereof, stainless steel, ceramics, biocompatible glass and combinations thereof.

6. The implant as recited in Claim 15 in which said orthonormal matrix is oriented diagonally relative to a major axis of the implant.

7. The implant as recited in Claim 14 in which said repetitive micro-geometric pattern of ridges and grooves comprises application to surfaces of said implant element in orientations which, relative to a longitudinal axis of said implant, are selected from the group consisting of vertical, horizontal, orthonormal diagonal, radial, circumferential, and concentric orientations.

9. The implant as recited in Claim 14¹ in which said orthopedic implant is selected from the group consisting hip, knee, shoulder, elbow, ankle and finger implants.

12. The implant as recited in claim 9 comprising different zones furnished with respectively different surface patterns.

13. The implant as recited in Claim 12 in which said different zones include respective hard and soft tissue contact zones

14. An orthopedic implant comprising an implant element for surgical insertion into a bone or bone-related tissue of a patient, said implant element comprising a micro-geometric, repetitive surface pattern in a form of a multiplicity of substantially parallel alternating ridges and grooves, each having an established width in a range of about 2 to about 25 microns, and an established depth in a range of about 2 to about 25 microns, whereby said micro-geometric repetitive pattern defines a guide for a promotion of rate, orientation and direction of growth of colonies of cells of said bone which are in contact with said surface pattern.

15. The implant as recited in Claim 14, in which said implant element comprises a grid-like matrix of said pattern of alternating ridges and grooves.

16. The implant as recited in Claim 14, in which said alternating ridges and grooves are oriented in parallel with a longitudinal axis of said implant.

17. The implant as recited in Claim 16, in which said alternating ridges and grooves are oriented transversely to said longitudinal axis of said implant.

18. The implant as recited in Claim 5, in which the surface of said implant element comprises a surface selected from the group of surfaces consisting of hydroxyapatite, RBM roughening, titanium, plasma, sprayed, calcium sulfate, biocompatible glass, collagen, growth factor compounds, and combination thereof.

19. The implant as recited in claim 9, in which said repetitive micro-geometric pattern comprises a product of the process group consisting of laser etching, acid etching, mechanical etching, and photolithography.